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EXAMINER	
ML, QIUWEN	
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1655	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/586,264	SCHWEIZER ET AL.	
	Examiner	Art Unit	
	QIUWEN MI	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 January 2009*.

2a)☒ This action is FINAL. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *7/18/2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment in the reply filed on 1/12/09 is acknowledged, with the cancellation of Claims 1-7, and 20-30. Claims 8-19 are pending. Claims 8-19 are examined on the merits.

Any rejection that is not reiterated is hereby withdrawn.

Specification/Abstract Objections

Specification

The disclosure remains objected to because of the following informalities: The specification recites "novel" on pages 1-5, 9, 16, 20, 27, and 30. It is suggested that the term "novel" be deleted from the language of the specification. Once the determination of the novelty of a claimed invention has been established and the disclosure of the invention made public and/or patented, the claimed invention is no longer novel or new, since the scope of the invention no longer embraces what is considered "novel". Thus, the incorporation of the term "novel" into the language of the specification is not appropriate. Correction is required.

Abstract

The abstract of the disclosure remains objected to for the following reasons: The abstract recites "novel canola protein" in lines 1, 7, and 13. It is suggested that the term novel be deleted from the language of the abstract. Once the determination of the novelty of a claimed invention

has been established and the disclosure of the invention made public and/or patented, the claimed invention is no longer novel, since the scope of the invention no longer embraces what is considered "novel". Thus, the incorporation of "novel" into the language of the abstract is not appropriate. Appropriate correction is required. Correction is required. See MPEP § 608.01(b).

Double Patent Rejections

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

1. Claims 8-19 remain provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 8-19 of copending Application No. 11/272,705. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Applicant argues that it is intended to delete claims 8-19 from copending application 11/272,705 (page 9, 2nd paragraph).

Since claims 8-19 from copending application 11/272,705 still exist, thus the rejection is maintained.

Claim Rejections –35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 8-19 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Logie et al (US 2004/0034200) in view of Hiron (US 2003/0224099).

This rejection is maintained for reasons of record set forth in the Office Action mailed out on 9/12/2008, repeated below. Applicants' arguments filed have been fully considered but they are not deemed to be persuasive.

Logie et al teach that the PMM (gelatinous gluten-like protein micellar mass)-derived canola protein isolate preferably has a protein component content of about 88 to about 98 wt % of 7S protein, about 1 to about 10 wt % of 12S protein and 0 to about 6 wt % of 2S protein while the supernatant-derived canola protein isolate preferably has a protein component content of about 70 to about 95 wt % of 2S protein, about 5 to about 30 wt % of 7S protein and 0 to about 2 wt % of 12S protein [0012] (thus an increased proportion of 2S canola protein). The present invention provides a canola protein isolate composition comprising (1) a first canola protein isolate having a protein content of at least about 90 wt %, preferably at least about 100 wt %, on a dry weight basis and at a Kjeldahl nitrogen conversion of N.times.6.25 and which exhibits a protein profile which is about 60 to about 98 wt % of 7S protein, about 1 to about 15 wt % of 12S protein and 0 to about 25 wt % of 2S protein [0016]. The aqueous protein solution resulting

from the high or low pH extraction step then is pH adjusted to the range of about 5 to about 6.8, preferably about 5.3 to about 6.2 [0048] . The concentrated protein solution resulting from the concentration step and optional defatting step then is diluted to effect micelle formation by mixing the concentrated protein solution with chilled water having the volume required to achieve the degree of dilution desired. Depending on the proportion of canola protein desired to be obtained by the micelle route and the proportion from the supernatant, the degree of dilution of the concentrated protein solution may be varied. With higher dilution levels, in general, a greater proportion of the canola protein remains in the aqueous phase [0055]. When it is desired to provide the greatest proportion of the protein by the micelle route, the concentrated protein solution is diluted by about 15 fold or less, preferably about 10 fold or less [0056]. The chilled water with which the concentrated protein solution is mixed has a temperature of less than about 15.degree. C., generally about 3.degree. to about 15.degree. C., preferably less than about 10.degree. C., since improved yields of protein isolate in the form of protein micellar mass are attained with these colder temperatures at the dilution factors used [0057]. The supernatant from the dilution step, following removal of the PMM, is concentrated to increase the protein concentration thereof. Such concentration is effected using any convenient selective membrane technique, such as ultrafiltration, using membranes with a suitable molecular weight cut-off permitting low molecular weight species, including the salt and other non-proteinaceous low molecular weight materials extracted from the protein source material, to pass through the membrane, while retaining canola protein in the solution. Ultrafiltration membranes having a molecular weight cut-off of about 3000 to 10,000 daltons, having regard to differing membrane materials and configuration, may be used. Concentration of the supernatant in this way also

reduces the volume of liquid required to be dried to recover the protein. The supernatant generally is concentrated to a protein concentration of about 100 to about 400 g/L, preferably about 200 to about 300 g/L, prior to drying. Such concentration operation may be carried out in a batch mode or in a continuous operation, as described above for the protein solution concentration step [0073]. The concentration step may be effected in any convenient manner consistent with batch or continuous operation, such as by employing any convenient selective membrane technique, such as ultrafiltration or diafiltration, using membranes, such as hollow-fibre membranes or spiral-wound membranes, with a suitable molecular weight cut-off, such as about 3000 to about 50,000 daltons, having regard to differing membrane materials and configurations, and, for continuous operation, dimensioned to permit the desired degree of concentration as the aqueous protein solution passes through the membranes [0050]. The molecular weight cut-off of the membrane is usually chosen to ensure retention of a significant proportion of the protein in the solution, while permitting contaminants to pass through having regard to the different membrane materials and configurations [0053]. The salt solubilization of the protein is effected at a temperature of at least about 5.degree. C. and preferably up to about 35.degree. C., preferably accompanied by agitation to decrease the solubilization time, which is usually about 10 to about 60 minutes. It is preferred to effect the solubilization to extract substantially as much protein from the oil seed meal as is practicable, so as to provide an overall high product yield [0033]. In a second set of experiments, 500 mL of water with no salt added was first heated to 60.degree. C. on a hot plate stirrer and then 50 g of canola oil seed meal which had been low temperature toasted at 100.degree. C. to remove residual solvent were added and stirred for 15 minutes while the temperature was maintained. The extract was separated from

the spent meal by centrifugation at 5000.times.g for 10 minutes (thus about 5-10 min) [0136] (thus heat treating the aqueous solution to cause precipitation of 7S canola protein, removing degraded 7S protein from aqueous solution; separating said aqueous protein solution from residual oil seed meal). The clarified aqueous protein solution is pumped by line 26 through ultrafiltration membrane 28 to produce a concentrated protein solution as the retentate in line 30 with the permeate being recovered by line 32. The concentrated protein solution is passed into a precipitation vessel 34 containing cold water fed by line 36. Protein micellar mass formed in the precipitation vessel 34 is removed by line 38 and passed through a spray dryer 40 to provide dry canola protein isolate 42 [0095]. The settled isolate is separated from the residual aqueous phase or supernatant, such as by decantation of the residual aqueous phase from the settled mass or by centrifugation. The PMM may be used in the wet form or may be dried, by any convenient technique, such as spray drying, freeze drying or vacuum drum drying, to a dry form. The dry PMM has a high protein content, in excess of about 90 wt % protein, preferably at least about 100 wt % protein (calculated as Kjeldahl N.times.6.25), and is substantially undenatured [0064]. The aqueous protein solution then is concentrated to increase the protein concentration thereof while maintaining the ionic strength thereof substantially constant [0049].

Logie et al do not teach a canola protein isolate consisting predominantly of 2S protein, neither do Logie et al explicitly teach the claimed temperature for heat treatment, the claimed amount of molecular weight-cut-off of the membrane, and the claimed amount of 7S protein to be degraded.

Hiron et al teach that in one aspect of the present invention, there is provided in a food composition comprising a foodstuff and at least one component providing functionality in said food composition, the improvement which comprises at least partially replacing said at least one component by a substantially undenatured canola protein isolate having a protein content of at least about 90 wt %, as determined by Kjeldahl nitrogen x 6.25 on a dry weight basis, said canola protein isolate exhibiting a protein profile which is about 60 to about 95 wt % of 2S protein (thus predominantly of 2S protein); about 5 to about 90 wt % of 7S protein; 0 to about 5 wt % of 12S protein [0015]. Hiron et al also teach that the canola protein isolate may be utilized in each of these applications to replace the protein commonly used to provide the specific functional properties. In general, the canola protein isolate can replace or extend the existing protein product. In addition, the canola protein isolate has a high quality amino acid profile, bland flavour profile and does not possess detrimental flavour characteristics nor nutritional factors which would adversely affect its employment in food product applications [0019].

It would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to use the 2S predominant canola protein from Hiron et al since Hiron et al teach that the canola protein isolate can replace or extend the existing protein product. And it has a high quality amino acid profile, bland flavour profile and does not possess detrimental flavour characteristics nor nutritional factors which would adversely affect its employment in food product applications. Since both of the invention of Logie et al and Hiron et al yielded beneficial results in making canola protein isolate, one of ordinary skill in the art would have been motivated to make the modifications and combine two inventions together. Regarding the

limitation to the claimed temperature for heat treatment, the claimed amount of molecular weight-cut-off of the membrane, or the claimed amount of 7S protein to be degraded, the result-effective adjustment in conventional working parameters is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Applicant argues that "There is no description in Logie et al of heat treating the supernatant from PMM formation, optionally in a concentrated form, to cause precipitation of 7S canola protein, as recited in claim 8, nor of effecting any such heat treatment step by heating the aqueous solution for about 5 to about 15 minutes at a temperature of about 75° to about 95°C, as recited in claim 11" (page 10, 2nd paragraph). Applicant further argues that "There is no evidence to suggest that extracting the canola oil seed meal (which contains the 2S and 7S proteins of canola) at elevated temperature (60°C) results in precipitation of 7S canola protein, in any event, any such result is irrelevant to applicants claims, which relate to an entirely different stage of the procedure of Logie et al. In Logie et al, the aqueous canola protein solution resulting from the extraction of canola oil seed meal with water is processed to recover PMM and a supernatant, from which further canola protein isolate, predominantly 2S protein, Is reovered. As described in Logie et al, where the canola oil seed meal is extracted with water (as in the Example referred to), salt is added to the aqueous canola protein solution to provide a salt concentration of at least

0.10 and preferably at least about 0.15 (see paragraphs 0046 and 0031). The salted aqueous canola protein solution then is processed as described by the Examiner in the Office Action with respect to Figure 1" (page 10, last paragraph bridging page 11).

This is not found persuasive. As indicated above, Logie et al teach in a second set of experiments, 500 mL of water with no salt added was first heated to 60.degree. C. on a hot plate stirrer and then 50 g of canola oil seed meal which had been low temperature toasted at 100.degree. C. to remove residual solvent were added and stirred for 15 minutes while the temperature was maintained. The extract was separated from the spent meal by centrifugation at 5000.times.g for 10 minutes (thus about 5-10 min) [0136] (Thus heat treating the aqueous solution to cause precipitation of 7S canola protein, removing degraded 7S protein from aqueous solution; separating said aqueous protein solution from residual oil seed meal). As discussed in MPEP § 2144, if the facts in a prior legal decision are sufficiently similar to those in an application under examination, the examiner may use the rationale used by the court. Examples directed to various common practices which the court has held normally require only ordinary skill in the art and hence are considered routine expedients are discussed below". In the instant case, Ex parte Rubin, 128 USPQ 440 (Bd. App. 1959) (Prior art reference disclosing a process of making a laminated sheet wherein a base sheet is first coated with a metallic film and thereafter impregnated with a thermosetting material was held to render prima facie obvious claims directed to a process of making a laminated sheet by reversing the order of the prior art process steps). See also In re Burhans, 154 F.2d 690, 69 USPQ 330 (CCPA 1946) (selection of any order of performing process steps is prima facie obvious in the absence of new or unexpected results); In re Gibson, 39 F.2d 975, 5 USPQ 230 (CCPA 1930) (Selection of any order of mixing

ingredients is prima facie obvious). Therefore, although the cited reference does not explicitly the claimed sequential steps in claim 8, since 7S protein was degraded by the heat treatment, and separated from 2S protein through centrifugation from the beginning, the canola protein isolate would necessarily have an increased proportion of 2S canola protein as claimed, and selection of any order of performing process steps is prima facie obvious in the absence of new or unexpected results.

Applicant argues that "It is submitted, for the reasons discussed above, that the Logle et al reference fails to disclose or suggest heat treatment of the supernatant from the PMM formation and precipitation of 7S protein therefrom. The Examiner is correct that the reference does not disclose the heat treatment conditions recited in claim 11 nor the degree of degradation of the quantity of 7S protein recited in claims 9 and 10" (page 11, 2nd paragraph from bottom).

As indicated above and in the previous Office Action, Logie et al do not explicitly teach the claimed temperature for heat treatment, however, Logie et al do teach the claimed heat treatment. It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. The differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie

obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); In re Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969) (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.). For more recent cases applying this principle, see Merck & Co. Inc. v. Biocraft Laboratories Inc., 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); In re Kulling, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990); and In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997). see MPEP § 2144.05 part II A. Although the prior art did not specifically disclose the claimed temperature for heat treatment, it would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal experimental conditions which would have been routinely determined and optimized in the pharmaceutical art.

Applicant argues that "The Examiner may wish to note that the specification of Hiron contains an error in both paragraph 0015 and claim 1 in specifying a range of about 5 to about ~ wt% for the 7S protein. The correct range is about 5 to about 40 wt%, as is evident from the Logie et al reference and the cross-reference thereto in paragraph 0012 of Hiron. (in addition, the

Examiner is referred to the corresponding granted US Patents Nos. 7,211,286 and 7,211,288) The Ganola protein isolate used in Hiron, therefore, is the same canola protein isolate as is the supernatant-derived canola protein isolate of Logie et al and consists predominantly of 2S canola protein. Having regard thereto, it would appear that the Hiron reference is superfluous in view of the disclosure of Logie et al" (page 12, 2nd paragraph).

This is not found persuasive. Since claims are part of the specification, therefore it is uncertain whether 5-90% is not the correct range. In addition, Hiron reference was brought in to show that it would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to use the 2S predominant canola protein from Hiron et al since Hiron et al teach that the canola protein isolate can replace or extend the existing protein product. As Hiron et al teach the 2S predominant canola protein has a high quality amino acid profile, bland flavour profile and does not possess detrimental flavour characteristics nor nutritional factors which would adversely affect its employment in food product applications.

Applicant's arguments have been fully considered but they are not persuasive, and therefore the rejections in the record are maintained.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Qiuwen Mi whose telephone number is 571-272-5984. The examiner can normally be reached on 8 to 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

QM

/Michele Flood/

Primary Examiner, Art Unit 1655